UCB and Ferring Pharmaceuticals Announce Co-Promotion of CIMZIA® (certolizumab pegol) for the Treatment of Adults with Moderate to Severe Crohn's Disease

- *Ferring joins with UCB to promote CIMZIA prefilled syringe for Crohn's disease in the U.S.*
- *Co-promotion strengthens commitment to patients living with Crohn's disease by reaching more gastroenterologists while also continuing patient support programs*
- *Ferring is expanding its focus in specialty areas within gastroenterology, demonstrating commitment to gut health*
- *UCB is preparing for future launches in immunology, demonstrating commitment to patients with severe chronic diseases*

Brussels, Belgium and Parsippany, USA – July 7, 2020 (7:00 p.m. CET and 1:00 p.m. ET) – UCB and Ferring Pharmaceuticals Inc. today announced they have entered into a co-promotion agreement to commercialize the prefilled syringe formulation of CIMZIA® (certolizumab pegol) in the United States, specifically for the treatment of Crohn's disease (CD). Ferring will take over marketing, sales promotion, and field medical affairs activities. UCB will continue to be responsible for all product-related activities, including revenue recognition. CIMZIA is an injectable biologic treatment option for adults with moderate to severe Crohn's disease with inadequate response to conventional therapy. UCB will continue to promote and to commercialize the lyophilized formulation of CIMZIA for all indications as well as the prefilled syringe formulation for CIMZIA's rheumatology and dermatology indications.

"UCB is committed to serving the needs of immunology patients, including those living with Crohn's disease. We are excited about this opportunity as it will expand the awareness to the benefits of CIMZIA for individuals living with moderate to severe Crohn's disease, while continuing to support patients through our services and programs," said Camille Lee, Head of U.S. Immunology at UCB. "We believe UCB and Ferring are a strategic fit for the co-promotion as both companies have a strong patient-focused commitment and Ferring has expertise in gastroenterology. UCB is preparing for future launches in immunology, demonstrating our commitment to patients with severe chronic diseases."

This co-promotion allows Ferring to expand its growing portfolio in the gastrointestinal space and support patients living with Crohn's disease, while enabling UCB to focus on and prepare for the future.

"Ferring is focusing on gut health as we expand our gastroenterology portfolio," said Brent Ragans, President of Ferring US. "Together with our existing portfolio, this agreement with UCB will allow Ferring to offer treatment options to the nearly 800,000 adult patients in the U.S. who suffer from Crohn's disease."

CIMZIA has been a treatment option for adults living with moderate to severe Crohn's disease over the last 12 years, since it was approved by the FDA in 2008 based on safety and efficacy data from clinical trials in more than 1,500 patients with Crohn's disease.

CIMZIA can be administered either through self-injection or by a healthcare professional.[1] CIMZIA can lower the ability to fight infections. Some people who received CIMZIA have developed serious infections, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body.[1] Some of these serious infections have caused hospitalization and death.[1]

About Crohn's disease

Crohn's disease is an inflammatory bowel disease causing chronic inflammation of the gastrointestinal (GI) tract.[2] Crohn's disease can affect any part of the GI tract from mouth to anus, most commonly involving the ileum and proximal colon.[3] It belongs to a group of conditions known as inflammatory bowel diseases, or IBD.[4] The disease can occur at any age, but is most often diagnosed in adolescents and adults between the ages of 20 and 30.[2] Approximately 780,000 Americans are currently affected by Crohn's disease.[3]

Patients with Crohn's disease may present acutely or have a history of symptoms prior to confirming diagnosis.[4] A hallmark symptom in patients with Crohn's disease is abdominal pain.[4] Other symptoms include diarrhea potentially persistent in nature, GI bleeding, urgent need to move bowels, abdominal cramps, sensation of incomplete bowel evacuation and constipation, which can lead to bowel obstruction.[4]

About CIMZIA® in the US

CIMZIA is the only Fc-free, PEGylated anti-TNF (Tumor Necrosis Factor). CIMZIA has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha.

CIMZIA is indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining

clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

CIMZIA is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), adults with active psoriatic arthritis (PsA), adults with active ankylosing spondylitis (AS), and adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

In addition, CIMZIA is indicated for the treatment of moderate to severe plaque psoriasis (PSO) in adults who are candidates for systemic therapy or phototherapy. See important safety information including risk of serious bacterial, viral and fungal infections and tuberculosis below.

IMPORTANT SAFETY INFORMATION about CIMZIA in the U.S.
CONTRAINDICATIONS

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

SERIOUS INFECTIONS

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.
- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Exercise caution and monitor carefully.

HYPERSENSITIVITY

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a plastic derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

DRUG INTERACTIONS

- Do not use CIMZIA in combination with other biological DMARDS.

AUTOIMMUNITY

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

ADVERSE REACTIONS

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were: upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

For full prescribing information, please visit
https://ucb-usa.com/_up/ucb_usa_com_kopie/documents/Cimzia_PI.pdf

References:

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About UCB
UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 7 600 people in approximately 40 countries, the company generated revenue of € 4.9 billion in 2019. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCBUSA

About Ferring Pharmaceuticals
Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. In the United States, Ferring is a leader in reproductive medicine and maternal health, and in specialty areas within gastroenterology and orthopaedics. For more information, call 1-888-FERRING (1-888-337-7464); visit www.FerringUSA.com

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